

PATENT
Docket No. 252312007400

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Jill A. Jacobson
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Matthew D. LINNIK et al.

Serial No.: 09/724,822

Filing Date: November 28, 2000

For: METHODS OF TREATING LUPUS
BASED ON ANTIBODY AFFINITY
AND SCREENING METHODS AND
COMPOSITIONS FOR USE THEREOF

Examiner: C. Qian

Group Art Unit: 1636

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

This Supplemental Information Disclosure Statement is submitted:

- ☒ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of ___ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of ___ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **252312007400**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 13, 2004

Respectfully submitted,

By: 

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Form PTO-1449

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**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

Applicant

Matthew D. LINNIK et al.

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Group Art Unit 1636

Mailing Date February 13, 2004


 (Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	08/02/2001	2001/0010818	Engle et al.			
	2.	06/19/2003	2003/0114405	Linnik et al.			
	3.	12/07/1993	5,268,454	Barstad et al.			
	4.	10/06/1998	5,817,752	Yu			
	5.	01/05/1999	5,856,464	Livingston			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	6.	12/19/1996	WO 96/40708	WIPO			
	7.	12/11/1997	WO 97/46248	WIPO			

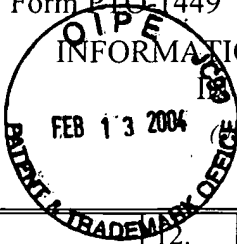
OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	
	8.	Alarcon-Segovia, D. et al. (2001). "SLE Trial Shows Fewer Renal Flares in LJP 394-Treated Patients with High-Affinity Antibodies to LJP 394:90-05 Trial Results," located at < http://www.ljpc.com/abstracts/abstract_2001_02.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
	9.	Alarcon-Segovia, D. et al. (2003). "LJP 394 for the Prevention of Renal Flare in Patients with Systemic Lupus Erythematosus: Results from a Randomized, Double-Blind, Placebo-Controlled Study," located at < http://www.ljpc.com/abstracts/abstract_2003_01.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
	10.	Alarcon-Segovia, D. et al. (2003). "SLE Trial Shows Fewer Renal Flares in LJP 394-Treated Patients with High-Affinity Antibodies to LJP 394:90-05 Trial Results," located at < http://www.ljpc.com/abstracts/abstract_2000_sle_trial.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
	11.	Alarcon-Segovia, D. et al. "SLE Trial Shows Fewer Renal Flares in LJP-394 Treated Patients with High-Affinity Antibodies to LJP-394: 90-05. Trial Results," <i>Lupus</i> 10 (Supplement 1):pS272: 1231.

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Form PTO-1449		Docket Number 252312007400	Application Number 09/724,822
 <p>INFORMATION DISCLOSURE CITATION ON AN APPLICATION</p> <p>(File several sheets if necessary)</p>		Applicant	
		Matthew D. LINNIK et al.	
		Filing Date November 28, 2000	Group Art Unit 1636
		Mailing Date February 13, 2004	
12.	Cardiel, M. (2003). "Randomized, Placebo Controlled, Double-Blind Phase III Clinical Trial for the Evaluation of LJP 394 (Abetimus Sodium) in the Treatment of Patients with SLE who are at Risk for Renal Flare," located at < http://www.ljpc.com/abstracts/abstract_2003_02.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.		
13.	Cardiel, M.H. et al. (2003). "Clinical Efficacy Results from a RCT of LJP 394 in SLE Patients with History of Renal Disease," <i>Arthritis and Rheumatism</i> 48(9):582-583.		
14.	Cardiel, M.H. et al. (2003). "Clinical Efficacy Results from a RCT of LJP 394 in SLE Patients with History of Renal Disease," located at < http://www.ljpc.com/abstracts/abstract_2003_07.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.		
15.	Furie, R.A. et al. (2000). "Treatment of Systemic Lupus Erythematosus with LJP 394," located at < http://www.ljpc.com/abstracts/abstract_2001_16.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.		
16.	Iverson et al. (1998) "A Chemically Defined, Toleragen-Based Approach for Targeting Anti- β_2 -glycoprotein I Antibodies" <i>Lupus</i> 7 (Suppl 2): S166-S169.		
17.	Iverson et al. (1998) "Anti- β_2 glycoprotein I (β_2 GPI) Autoantibodies Recognize an Epitope on the First Domain of β_2 GPI" <i>Proc Natl Acad Sci USA</i> 95:15542-15546.		
18.	Jones et al. (1998) "Synthesis of a Cyclic-Thioether Peptide which Binds Anti-Cardiolipin Antibodies" <i>Tetrahedron Letters</i> 39:6107-6110.		
19.	Jones, D. (1991). "Case Study: Lupus Nephritis," <i>American Nephrology Nurses' Association</i> 18(3):327-329.		
20.	Jones, D. (1994). "A New Oligonucleotide Conjugate for Suppression of Anti-Double Stranded DNA Antibodies," <i>Abstracts of Papers American Chemical Society</i> 207(1-2):pBIOT 113.		
21.	Kandiah et al. (1998) "Current Insights into the "Antiphospholipid" Syndrome: Clinical, Immunological, and Molecular Aspects" <i>Advances in Immunology</i> 70:507-563.		
22.	La Jolla Pharmaceutical Co. Press Release. (March 31, 2003). "Results from Two Riquent TM Trials Show Lupus Patients with Sustained Reductions in Antibodies to dsDNA Have Fewer Renal Flares," San Diego, CA. 4 pages.		
23.	Linnik, M.D. et al. (2000). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients with Positive dsDNA Antibody Titers," <i>Arthritis and Rheumatism</i> 43(9):1045.		
24.	Linnik, M.D. et al. (2000). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients with Positive dsDNA Antibody Titers," located at < http://www.ljpc.com/abstracts/abstract_2000_affinity.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.		
25.	Linnik, M.D. et al. (2000). "Effect of LJP 394 on Patients with Greatest Impairment of Renal Function at Baseline in the 90-05 Trial," <i>Arthritis and Rheumatism</i> 43(9):1046.		
26.	Linnik, M.D. et al. (2000). "Effect of LJP 394 on Patients with Greatest Impairment of Renal Function at Baseline in the 90-05 Trial," located at < http://www.ljpc.com/abstracts/abstract_2000_effect.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.		
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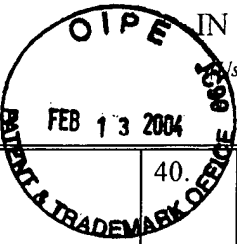
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| 27. | Linnik, M.D. et al. (2000). "Reduction in Anti-dsDNA Antibodies by LJP 394 in Lupus Patients is Influenced by Affinity for the LJP 394 dsDNA Eptiope," located at < http://www.ljpc.com/abstracts/abstract_2000_reduction.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages. |
| 28. | Linnik, M.D. et al. (2001). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients," located at < http://www.ljpc.com/abstracts/abstract_2001_04.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page. |
| 29. | Linnik, M.D. et al. (2001). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients," <i>Lupus</i> 10(Supplement 1):pS52:30. |
| 30. | Linnik, M.D. et al. (2001). "Effect of LJP 394 on SLE Patients with Impaired Renal Function," located at < http://www.ljpc.com/abstracts/abstract_2001_03.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page. |
| 31. | Linnik, M.D. et al. (2001). "Effect of LJP 394 on SLE Patients with Impaired Renal Function," <i>Lupus</i> 10(Supplement 1):pS17:19. |
| 32. | Linnik, M.D. et al. (2001). "Effect of LJP 394 or High Dose Corticosteroids and Cyclophosphamide on Anti-dsDNA Antibodies in SLE Patients," located at < http://www.ljpc.com/abstracts/abstract_2001_09.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages. |
| 33. | Linnik, M.D. et al. (2001). "Effect of LJP or High Dose Corticosteroids and Cyclophosphamide on Anti-dsDNA Antibodies in SLE Patients," <i>Arthritis and Rheumatism</i> 44(9):S282:1378. |
| 34. | Linnik, M.D. et al. (2002). "Workshop Report on Some New Ideas About the Treatment of Systemic Lupus Erythematosus" <i>Lupus</i> 11:793-796. |
| 35. | Linnik, M.D. et al. (2002). "Effect of LJP 394 or High Dose Corticosteroids and Cyclophosphamide on Anti-dsDNA Antibodies in SLE Patients," located at < http://www.ljpc.com/abstracts/abstract_2002_05.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages. |
| 36. | Linnik, M.D. et al. (2002). "Effect of LJP 394, High Dose Corticosteroids and Cyclophosphamide (HDCC) on Anti-dsDNA Antibodies in SLE Patients," located at < http://www.ljpc.com/abstracts/abstract_2002_02.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page. |
| 37. | Linnik, M.D. et al. (2002). "Reduction in Antibodies to dsDNA Using LJP in Dose Ranging Trial in Lupus Patients," located at < http://www.ljpc.com/abstracts/abstract_2002_01.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page. |
| 38. | Linnik, M.D. et al. (2002). "Workshop Report on Some New Ideas about the Treatment of Systemic Lupus Erythematosus," located at < http://www.ljpc.com/abstracts/abstract_2002_10.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page. |
| 39. | Linnik, M.D. et al. (2003). "Reductions in Anti-DSDNA Antibodies and Reduced Risk of SLE Renal Flare and Major SLE Flare," located at < http://www.ljpc.com/abstracts/abstract_2003_09.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages. |

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	40.	Linnik, M.D. et al. (2003). "SLE Patients with Sustained Reductions in Anti-DSDNA Antibodies Have a Reduced Risk of Renal Flare and Major SLE Flare," located at < http://www.ljpc.com/abstracts/abstract_2003_05.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	41.	McNeeley, P.A. et al. (2000). "Lupus Patient Pharmacodynamic Response to LJP 394 is Influenced by Pre-Treatment Antibody Affinity for LJP 394," located at < http://www.ljpc.com/abstracts/abstract_2000_pharmaco_response.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	42.	McNeeley, P.A. et al. (2001). "Pre-Treatment Affinity for LJP 394 Influences Pharmacodynamic Response in Lupus Patients," located at < http://www.ljpc.com/abstracts/abstract_2001_13.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.	
	43.	Morimoto, C. et al. (1982). "Correlation Between Clinical Activity of Systemic Lupus Erythematosus and the Amounts of DNA in DNA/Anti-DNA Antibody Immune Complexes," <i>J. Immunol.</i> 139(5):1960-1965.	
	44.	Morimoto, C. et al. (1987). "A Defect of Immunoregulatory T Cell Subsets in Systemic Lupus Erythematosus Patients Demonstrated with Anti-2H4 Antibody," <i>J Clin Invest.</i> 79(3):762-768.	
	45.	Saffran, D.C. et al. (2002). "Treatment of Antibody-Mediated SLE-Like Disease in Male BXSB Mice with a B-Cell Toleragen Specific for Anti-dsDNA Antibodies," located at < http://www.ljpc.com/abstracts/abstract_2002_04.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.	
	46.	Sem, D.S. et al. (1998). "Structural Characterization and Optimization of Anti-body Selected Phage Library Mimotopes of an Antigen Associated with Autoimmune Recurrent Thrombosis," <i>Biochemistry</i> 37(46):16069-16091.	
	47.	Tumlin, J.A. et al. (2001). "The B-Cell Toleragen LJP-394 Reduces Renal Flares in Patients with Lupus Nephritis: A Prospective Double-Blinded, Placebo Controlled Trial," located at < http://www.ljpc.com/abstracts/abstract_2001_08.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	48.	Tumlin, J.A. et al. (2001). "The B-Cell Toleragen LJP-394 Reduces Renal Flares in Patients with Lupus Nephritis: A Prospective, Double-Blinded, Placebo Controlled Trial," <i>Journal of the American Society of Nephrology</i> 12:p253A.	
	49.	Tumlin, J.A. et al. (2003). "Efficacy Results from a RCT of LJP 394 in SLE Patients with History of Renal Disease," located at < http://www.ljpc.com/abstracts/abstract_2003_10.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	50.	Tumlin, J.A. et al. (2003). "Renal Flare in SLE Patients with Impaired Renal Function in a RCT of LJP 394," located at < http://www.ljpc.com/abstracts/abstract_2003_12.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
51.	Wallace, D.J. et al. (2003). "Safety Results from a Randomized Controlled Trial (RCT) of LJP 394 in Systemic Lupus Erythematosus (SLE) Patients with a History of Renal Disease," located at < http://www.ljpc.com/abstracts/abstract_2003_06.html > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.		
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52.

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